

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

September 23, 2019

Tim McGonegal Scientific Coordination Inc. Agent to Summit Chemical Co. DBA Summit Responsible Solutions 7303 Lake Willow Ct. Warrenton, VA 20187

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – adding use

site, expiration statement, PPE to sublabel B, optional marketing claims, and product

information table

Product Name: DUNKS

EPA Registration Number: 6218-87 Application Date: 04/25/2019 OPP Decision Number: 551821

Dear Mr. McGonegal:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration

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process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Cody Kendrick by phone at (703) 347-0468 or via email at kendrick.cody@epa.gov.

Sincerely,

Seiichi Murasaki, Senior Regulatory Advisor

Microbial Pesticides Branch

Biopesticides and Pollution Prevention Division (7511P)

Office of Pesticide Programs

Enclosure: Stamped Label

[Text in brackets [] indicates optional language or language intended for explanatory purposes to facilitate label review. Thus, this language will often not appear on final printed labeling.]

[MASTER LABEL]

[Sublabel A: Residential Use Labeling]

[Sublabel B: Commercial/Professional Use Labeling]

ACCEPTED

Sep 23, 2019

Under the Federal Insecticide, Fungicide and Rodenticide Act as amended, for the pesticide registered under EPA Reg. No. 6218-87

[Sublabel A: Residential Use Labeling]

DUNKS® Alternative Brand Names: [SUMMIT B.t.i. MOSQUITO BRIQUETS] [SUMMIT B.t.i. MOSQUITO CHUNKS®] [SUMMIT B.t.i. CHUNKS®] [CHUNKS®], [DUNK CHUNKS®], [MOSQUITO CHUNKS®] [MOSQUITO DUNK CHUNKS®] [SUMMIT B.t.i MOSQUITO BRIQUET CHUNKS®]

SEGMENTED MOSQUITO DUNKS® FOR EASE OF USE

Controls Mosquito Larvae That May Spread Zika, Chikungunya, West Nile Virus, Dengue, and Yellow Fever

FLOATING, SUSTAINED-RELEASE LARVICIDE FOR LONG-TERM BIOLOGICAL CONTROL OF MOSQUITO LARVAE

**Kills Mosquitoes Before They're Old Enough To Bite!®

**For use on mosquito larvae

ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. Israelensis, Strain SUM-6218, solids, spores,	
and insecticidal toxins*	10.31%
OTHER INGREDIENTS:	89.69%
TOTAL	100.00%

^{*}Potency: 722 Aedes aegypti Units per milligram product. The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for first aid, additional precautionary statements, and directions for use. See the directions for use for specific application instructions.

Net Weight: xxxx

Not for sale or use after [date stamped is 6 months after the date of manufacture]

EPA Reg. No. 6218-87; Batch No. XXXX; EPA Est. No. 6218-MD-2

For Prevention and Control of Mosquito Larvae, Place DUNKS® in the Following Contained Standing Water Sites:

Flower Pots and Saucers • Funeral Urns • Gutters • Rain Barrels Used to Irrigate Plants and for Fish • Discarded Tires • Woodland Pools • Small Marshes • Lake Perimeters • Catch Basins • Roof and Street Gutters • Storm and Flood Water Retention Ponds • Plant and Fish Water Gardens and Ponds • Fish Farms • Bird Baths • Tree Holes • Unused Swimming Pools (Above and In-Ground) • Standing and Irrigation Water in Greenhouses • Sewage Ponds • Roadside Ditches • Cisterns and Water Supply Tanks • Animal and Livestock Watering Troughs • Aquaponics • Hydroponics • Agricultural Crop Irrigation water • Pastures, and other water habitats where mosquito larvae occur • Rice fields

Can Be Used In Plant and Fish Habitats

	FIRST AID
IF INHALED:	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	 Hold eye open, and rinse slowly and gently with water for 15- 20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.
	HOTI INE NUMPER

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor or when going for treatment. For non-emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu). For emergencies, call your local poison control center at 1-800-222-1222.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with eyes or clothing. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco, or using the toilet.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

May only be applied to contained water sources in the State of New York

Do not apply directly to treated, finished drinking water reservoirs.

PRODUCT INFORMATION

DUNKS® are formulated to release effective levels of *Bt israelensis* (*Bti*) for a period of 30 days under typical conditions. The floating action of DUNKS® will ensure that *Bti* is released at the surface and that it also gradually settles to the bottom.

DUNKS® can be used in mosquito breeding areas as specified on this label. To prevent DUNKS® from being flushed out of certain treatment sites, they can be anchored using a string tied through the hole in the center or staked in place with a small stick.

DUNKS® can also be used for pre-flood treatment. If DUNKS® are applied to dry areas, which are known or thought to become mosquito breeding sites when flooded, including temporary woodland pools and abandoned swimming pools, they will float to the surface when flooding occurs and start releasing *Bti*. Alternate wetting and drying will not reduce their effectiveness.

APPLICATION INSTRUCTIONS

MOSQUITO LARVAE

Flooded Mosquito Larval Breeding Sites (Outdoor Use): Apply DUNKS® to the sites listed on this label and according to the dosage table. In highly polluted water with a high organic content, such as sewage ponds, the application rate can be increased to as much as four (4) times the normal dosage based upon evaluation by the user of water organic content and/or seeing mosquito larvae in the water.

When mosquito larval populations are high, aquatic vegetation dense, or the water highly polluted at the time of DUNKS® use, pre-treatment with Summit® *B.t.i.* Granules or MOSQUITO BITS® is suggested. DUNKS® will then suppress mosquito larval development for up to 30 days. Some mosquito larvae that hatch after DUNKS® application may partially develop before dying. Allow a minimum of 48 hours for control.

Flooded Mosquito Larval Breeding Sites (Indoor Use): For use in areas that collect water from time to time, such as elevator shafts, basements that flood, sump pump wells and any drainage areas with standing water or subject to flooding within buildings. Apply DUNKS® according to the dosage table.

<u>Pre-Flood Treatment</u>: DUNKS® can be applied to the sites listed on this label when they are dry and in anticipation of them becoming flooded after rain. Use the correct amount of DUNKS® according to the dosage table.

<u>Evaporative Coolers</u>: Apply one DUNK[®] [4 Dunk Chunks®] per 100 square feet of cooler box. For smaller coolers, refer to the dosage table for the appropriate application rate.

DOSAGE TABLE

Surface Area of Standing Water	1 to 25 square feet	>25 to 50 square feet	>50 to 75 square feet	>75 to 100 square feet
Use Quantity	1/4 Dunk [®] , [1 DUNK CHUNKS [®]]	½ Dunk [®] , [2 DUNK CHUNKS [®]]		1 Dunk [®] , [4 DUNK CHUNKS [®]] per 100 square feet

STORAGE AND DISPOSAL			
Do not contam	Do not contaminate water, food, or feed by storage or disposal.		
PESTICIDE	Store DUNKS® in closed container with product labeling. Store in		
STORAGE:	cool, dry, and well-ventilated place inaccessible to children and pets.		
PESTICIDE	Non-refillable container. Do not reuse or refill this container. IF		
DISPOSAL	EMPTY: Place in trash or offer for recycling, if available. IF PARTLY		
AND	FILLED: Call your local solid waste agency for disposal instructions.		
CONTAINER	Never place unused product down any indoor or outdoor drain.		
HANDLING:			

SUMMIT® Chemical Co.

...responsible solutions®

235 S. KRESSON STREET BALTIMORE, MD 21224-2616 U.S. Patent No. 4.631.857

Patented in Canada, 1987 ®Registered Trademark of Summit Chemical Co.

OPTIONAL MARKETING CLAIMS:

- [USE IN BIRD BATHS, FISH PONDS, STOCK TANKS, RAIN BARRELS ANY STANDING WATER.]
- [DUNKS® BIOLOGICAL MOSQUITO LARVAE CONTROL MAY BE USED AROUND PEOPLE, PETS, FISH & LIVESTOCK]
- [TREATS (#CHUNKS) X (25 SQUARE FEET)] FOR EXAMPLE: [TREATS 125 SQUARE FEET*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 5 CHUNKS)

[TREATS 250 SQUARE FEET*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 10 CHUNKS)

• [X DAYS OF TREATMENT = (#OF CHUNKS) X (30 DAYS)

FOR EXAMPLE: [150 DAYS OF TREATMENT*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 5 CHUNKS)

[300 DAYS OF TREATMENT*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 10 CHUNKS)

- [KILLS MOSQUITO LARVAE FOR 30 DAYS]
- [CONTROLS MOSQUITO LARVAE FOR 30 DAYS]
- [BIOLOGICAL MOSQUITO LARVAE CONTROL]
- [KILLS MOSQUITO LARVAE]
- [CAN BE APPLIED TO WATER FOR EDIBLE PLANTS]
- [USE IN GARDENS WITH FRUITS AND VEGETABLES]

	PRODUCT FACTS
WHAT IT IS:	Continuous, Sustained Release Biological Larval Mosquito Control
WHAT IT DOES:	Kills Mosquito Larvae in Standing Water
WHERE TO USE:	Standing Water Serving as a Mosquito Breeding Sites, such as, Flower Pots and Saucers • Funeral Urns • Gutters • Rain Barrels Used to Irrigate Plants and Gardens • Discarded Tires • Woodland Pools • Marshes • Lake Perimeters • Catch Basins • Storm and Flood Water Retention Ponds • Plant and Fish Water Gardens and Ponds • Fish Farms • Bird Baths • Tree Holes • Un-used Swimming Pools (Above and In-Ground) • Irrigation Water • Greenhouses • Sewage Ponds • Waste Water Treatment Facilities • Self Watering Planters • Drainage Ditches • Cisterns and Water Supply Tanks • Animal and Livestock Watering Troughs • Pet Bowls • Aquaponics • Hydroponics • Agricultural Crop Irrigation Water • Pastures and other water habitats where mosquito larvae occur.
COVERAGE:	Each DUNK® Treats Up to 100 Square Feet [Each Dunk Chunk® Treats Up to 25
	Square Feet] of Surface Water or Area for 30 days.
QUESTIONS AND COMMENTS:	Call 1-800-227-8664 or email info@summitchemical.com

See insert for first aid, complete precautionary statements and directions for use. See the Directions for use for specific application instructions. [For small package labeling]

[Sublabel B: Commercial/Professional Use Labeling]

DUNKS[®] Alternate Brand Names: [SUMMIT B.t.i MOSQUITO BRIQUETS] [SUMMIT B.t.i. MOSQUITO CHUNKS[®]] [SUMMIT B.t.i. CHUNKS[®]] [SUMMIT B.t.i. MOSQUITO BRIQUET CHUNKS[®]] [CHUNKS[®]], [DUNK CHUNKS[®]], [MOSQUITO CHUNKS[®]] [MOSQUITO DUNK CHUNKS[®]]

SEGMENTED B.t.i BRIQUETS FOR EASE OF USE

Controls Mosquito Larvae That May Spread Zika, Chikungunya, West Nile Virus, Dengue, and Yellow Fever

FLOATING, SUSTAINED-RELEASE LARVICIDE FOR LONG-TERM BIOLOGICAL CONTROL OF MOSQUITO LARVAE.

**Kills Mosquitoes Before They're Old Enough To Bite!®

**For use on mosquito larvae

ACTIVE INGREDIENT:

Bacillus thuringiensis subsp. israelensis, Strain SUM-6218, solids, spores,	
and insecticidal toxins*	10.31%
OTHER INGREDIENTS:	89.69%
TOTAL	100.00%

^{*}Potency: 722 Aedes aegypti Units per milligram product. The percent active ingredient does not indicate product performance and potency measurements are not federally standardized.

KEEP OUT OF REACH OF CHILDREN CAUTION

See back panel for first aid, additional precautionary statements, and directions for use. See the directions for use for specific application instructions.

Net Weight: 8.8 oz. (20 DUNKS® - 0.44 oz. each), 1.6 KG

Not for sale or use after [date stamped is 6 months after the date of manufacture]

EPA Reg. No. 6218-87; Batch No. XXXX; EPA Est. No. 6218-MD-2

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Flower Pots and Saucers • Funeral Urns • Gutters • Rain Barrels Used to Irrigate Plants • Discarded Tires • Woodland Pools • Small Marshes • Lake Perimeters • Catch Basins • Roof and Street Gutters • Storm and Flood Water Retention Ponds • Plant and Fish Water Gardens and Ponds • Fish Farms • Bird Baths • Tree Holes • Unused Swimming Pools (Above and In-Ground) • Standing and Irrigation Water in Greenhouses • Sewage Ponds • Roadside Ditches • Cisterns and Water Supply Tanks • Animal and Livestock Watering Troughs • Aquaponics • Hydroponics • Agricultural Crop Irrigation water • Pastures, and other water habitats where mosquito larvae occur • Rice fields

Can Be Used In Plant and Fish Habitats

	FIRST AID
IF INHALED:	 Move person to fresh air. If person is not breathing, call 911 or an ambulance, then give artificial respiration, preferably by mouth-to-mouth if possible. Call a poison control center or doctor for further treatment advice.
IF IN EYES:	 Hold eye open, and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after the first 5 minutes, then continue rinsing eye. Call a poison control center or doctor for treatment advice.

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Have the product container or label with you when calling a poison control center or doctor or when going for treatment. For non-emergency information concerning this product, call the National Pesticide Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu). For emergencies, call your local poison control center at 1-800-222-1222.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION: Harmful if inhaled. Causes moderate eye irritation. Avoid breathing dust. Avoid contact with eyes or clothing. Remove and wash contaminated clothing before reuse. Wash thoroughly with soap and water after handling and before eating, drinking, and chewing gum, using tobacco, or using the toilet.

PERSONAL PROTECTIVE EQUIPMENT (PPE)

- Applicators and other handlers must wear:
- Long-sleeved shirt and long pants
- Waterproof gloves
- Shoes plus socks
- Protective eyewear
- A NIOSH-approved particulate respirator with any N, P, or R filter with NIOSH approval number prefix TC-84A or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. (Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.)

Follow the manufacturer's instructions for cleaning/maintaining PPE. If no such instructions are available for washables, use detergent and hot water. Keep and wash PPE separately from other laundry.

USER SAFETY RECOMMENDATIONS

Users should:

- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Do not apply directly to treated, finished drinking water reservoirs.

PRODUCT INFORMATION

DUNKS® are formulated to release effective levels of *Bt israelensis* (*Bti*) for a period of 30 days under typical conditions. The floating action of DUNKS® will ensure that *Bti* is released at the surface and that it also gradually settles to the bottom.

DUNKS® can be used in mosquito breeding areas as specified on this label.

DUNKS® can also be used for pre-flood treatment. If DUNKS® are applied to dry areas, which are known or thought to become mosquito breeding sites when flooded, including temporary woodland pools and abandoned swimming pools, they will float to the surface when flooding occurs and start releasing *Bti*. Alternate wetting and drying will not reduce their effectiveness.

APPLICATION INSTRUCTIONS

MOSQUITO LARVAE

Flooded Mosquito Larval Breeding Sites (Outdoor Use): Apply DUNKS® to the sites listed on this label and according to the dosage table. In highly polluted water with a high organic content, such as sewage ponds, the application rate can be increased to as much as four (4) times the normal dosage based upon evaluation by the user of water organic content and/or seeing mosquito larvae in water.

When mosquito larval populations are high, aquatic vegetation dense, or the water highly polluted at the time of DUNKS® use, pre-treatment with Summit® *B.t.i.* Granules or MOSQUITO BITS® is suggested. DUNKS® will then suppress mosquito larval development for up to 30 days. Some mosquito larvae that hatch after DUNKS® application may partially develop before dying. Allow a minimum of 48 hours for control.

<u>Flooded Mosquito Larval Breeding Sites (Indoor Use)</u>: For use in areas that collect water from time to time, such as elevator shafts, basements that flood, sump pump wells and any drainage areas with standing water or subject to flooding within buildings. Apply DUNKS® according to the dosage table.

<u>Pre-Flood Treatment</u>: DUNKS[®] can be applied to the sites listed on this label when they are dry and in anticipation of them becoming flooded after rain. Use the correct amount of DUNKS[®] according to the dosage table.

<u>Evaporative Coolers</u>: Apply one DUNK[®] [4 Dunk Chunks®] per 100 square feet of cooler box. For smaller coolers, refer to the dosage table for the appropriate application rate.

DOSAGE TABLE

Surface Area of Standing Water		-	I	>75 to 100 square feet
	½ Dunk [®] , [1 DUNK CHUNKS [®]]	DUNK CHUNKS®]	DUNK -	1 Dunk [®] , [4 DUNK CHUNKS [®]] per 100 square feet

[For the 20 DUNKS® package only:]

<u>PSYCHODID FLY LARVAE</u> (Filter Flies, Sewage Flies, and Drain Flies)

<u>Wastewater Treatment Plants</u>: Place one hundred twenty (120) DUNKS® in a perforated basket, such as a minnow bait basket, and suspend the basket in the wastewater stream before the water enters the trickling filter. Check the basket every day or every other day. Flowing water will slowly disperse the DUNKS® Keep the basket continuously filled with DUNKS® to ensure a steady flow of *Bti* into the filter. The number of DUNKS® needed for continuous, effective treatment will vary and is dependent on the volume and flow rate in each respective facility. The optimum quantity for control must be determined by user monitoring and experience.

	STORAGE AND DISPOSAL
Do	not contaminate water, food, or feed by storage or disposal.
PESTICIDE	Store DUNKS [®] in closed container with product labeling. Store in cool,
STORAGE:	dry, and well-ventilated place inaccessible to children and pets.
PESTICIDE DISPOSAL:	To avoid waste, use all material in this container by application according to label directions. If waste cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).
CONTAINER HANDLING:	Nonrefillable container. Do not reuse or refill this container. Offer for recycling if available, or dispose of in a sanitary landfill or by other procedures approved by state and local authorities.

SUMMIT® Chemical Co.
...responsible solutions®
235 S. KRESSON STREET
BALTIMORE, MD 21224-2616
U.S. Patent No. 4,631,857
Patented in Canada, 1987

[®]Registered Trademark of Summit Chemical Co.

OPTIONAL MARKETING CLAIMS:

- [USE IN BIRD BATHS, FISH PONDS, STOCK TANKS, RAIN BARRELS ANY STANDING WATER.]
- [DUNKS® BIOLOGICAL MOSQUITO LARVAE CONTROL MAY BE USED AROUND PEOPLE, PETS, FISH & LIVESTOCK]
- [TREATS (#CHUNKS) X (25 SQUARE FEET)] FOR EXAMPLE: [TREATS 125 SQUARE FEET*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 5 CHUNKS)

[TREATS 250 SQUARE FEET*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 10 CHUNKS)

• [X DAYS OF TREATMENT = (#OF CHUNKS) X (30 DAYS)

FOR EXAMPLE: [150 DAYS OF TREATMENT*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 5 CHUNKS)

[300 DAYS OF TREATMENT*]

[*PER PACKAGE] (APPLIES TO PACKAGE OF 10 CHUNKS)

- [KILLS MOSQUITO LARVAE FOR 30 DAYS]
- [CONTROLS MOSQUITO LARVAE FOR 30 DAYS]
- [BIOLOGICAL MOSQUITO LARVAE CONTROL]
- [KILLS MOSQUITO LARVAE]
- [CAN BE APPLIED TO WATER FOR EDIBLE PLANTS]
- [USE IN GARDENS WITH FRUITS AND VEGETABLES]

	PRODUCT FACTS
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QUESTIONS AND COMMENTS:	Call 1-800-227-8664 or email info@summitchemical.com

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See the Directions for use for specific application instructions. [For small package labeling]